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Attorneys for Defendant
GLAXOSMITHKLINE LLC, erroneously served and sued herein as SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STEPHEN WENDELL & LISA WENDELL, his wife, for themselves and as successors in interest to MAXX WENDELL, deceased,

Plaintiffs,

vs.

JOHNSON & JOHNSON; CENTOCOR, INC.; ABBOTT LABORATORIES; SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICALS USA; GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA; PAR PHARMACEUTICAL, INC.

Defendants.

Case No. 4:09-cv-04124-CW
Hon. Claudia Wilken
Courtroom 2

GLAXOSMITHKLINE LLC, formerly known as and served and sued herein as SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES

[FED. R. CIV. PROC. 56]

[DECLARATION OF WILLIAM A. HANSSEN; AND [PROPOSED] ORDER FILED CONCURRENTLY HEREWITH]

Hearing Date: August 11, 2011
Hearing Time: 2:00 p.m.
Hearing Location: Courtroom 2

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TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on August 11, 2011 at 2:00 p.m., or as soon thereafter as counsel may be heard, Defendant GLAXOSMITHKLINE LLC, formerly known as and served and sued herein as SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE ("GSK") will, and hereby does, move for summary judgment before the Hon. Claudia Wilken at the United States District Courthouse, Northern District, located at 1301 Clay Street, Courtroom 2, Oakland, California 94612.

GSK respectfully moves for summary judgment pursuant to Rule 56 of the *Federal Rules of Civil Procedure* on all claims for relief asserted by Plaintiffs STEPHEN WENDELL and LISA WENDELL, his wife, for themselves and as successors-in-interest to MAXX WENDELL, deceased ("Plaintiffs") against GSK, on the grounds that there is no genuine issue as to any material fact as to the two claims for relief alleged against GSK, both of which are based on a theory of failure to warn. GSK is entitled to judgment as a matter of law because Plaintiffs cannot establish a causal link between their alleged injury and GSK's conduct. Dr. Edward Rich prescribed mercaptopurine (a/k/a 6-mercaptopurine or 6-MP), to Mr. Wendell with knowledge of the alleged risk of hepatosplenic T-cell lymphoma ("HSTCL"), the specific risk Plaintiffs allege was reported with Purinethol®, GSK's brand name for mercaptopurine.[1] Thus, Plaintiffs cannot prove a necessary element of their causes of action, that GSK's allegedly inadequate warnings caused their injuries.

GSK's motion is based upon this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the Declaration of William A. Hanssen and all exhibits thereto, and all pleadings and papers on file in this

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[1] It was undisputed in GSK's prior motion for summary judgment, which was denied without prejudice, [Docket No. 150] that GSK transferred ownership of the New Drug Application for Purinethol® and all U.S. rights under the Application, including the right to distribute Purinethol®, effective July 1, 2003.

action, and upon such other matters as may be presented to the Court at the time of the hearing.

DATED: July 7, 2011

DRINKER BIDDLE & REATH LLP

By: _____
William A. Hanssen
Suzanne V. Stouder

Attorneys for Defendant
GLAXOSMITHKLINE LLC,
erroneously served and sued herein as
SMITHKLINE BEECHAM
d/b/a GLAXOSMITHKLINE

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiffs' Fourth Amended Complaint has two claims for relief sounding in negligence and strict liability alleged against GSK based on a theory of failure to warn. (FAC, ¶¶89-108.) GSK's motion for summary judgment on these claims should be granted because the undisputed material facts establish, as a matter of law, that the alleged failure to warn on which Plaintiffs' claims against GSK are based was not the proximate cause of Plaintiffs' alleged injuries. Both claims are predicated on an alleged failure to warn of a claimed risk of hepatosplenic T-cell lymphoma ("HSTCL") in pediatric patients reported with using Purinethol® (mercaptopurine). In order for these claims to survive a motion for summary judgment, Plaintiffs must establish not only that GSK failed to provide an adequate warning of the alleged risk, but that the purported failure to warn was the proximate cause of their alleged injuries. The testimony of the prescribing physician in this case, Dr. Edward Rich, unequivocally establishes, however, that he was aware of the ***precise risk*** Plaintiffs describe in their Fourth Amended Complaint ("FAC") when prescribing mercaptopurine. Furthermore, Dr. Rich testified that he did not recall reading or relying upon the mercaptopurine label in deciding to prescribe it to Mr. Wendell and decided to prescribe mercaptopurine to Mr. Wendell based on independent sources of information. In light of this testimony, Plaintiffs cannot establish that a different warning would have changed Dr. Rich's decision to prescribe mercaptopurine. Accordingly, Plaintiffs cannot prove causation, an essential element of both of their claims against GSK, and both claims fail as a matter of law.

Under California's learned intermediary doctrine, Plaintiff has the burden of proving that a different warning would have changed Dr. Rich's decision to prescribe Purinethol®. Plaintiffs' case against GSK fails because Dr. Rich's

testimony affirmatively establishes that the warning Plaintiffs urge was required would have had no impact on his decision to prescribe the medication.

Dr. Rich testified that he learned about the off label use of mercaptopurine to treat IBD during his pediatric gastroenterology fellowship. He prescribed mercaptopurine to Mr. Wendell based on information he learned during his fellowship training, from patient experience, by reading the medical literature and by attending conferences and meetings of pediatric gastroenterologists, but has no recollection of reading the labeling for mercaptopurine or relying upon it in making prescribing decisions. He keeps current about the changing information about potential risks reported with medications he prescribes, including mercaptopurine, through information he receives from attending conferences and meetings of pediatric gastroenterologists, discussions with gastroenterologist colleagues, and by reading case reports, reports of clinical studies, and articles published in the field. Dr. Rich learned of the early cases of HSTCL in patients taking Remicade® (a TNF inhibitor) in combination with mercaptopurine and other immunosuppressants in 2005 through his review of the literature. He testified unequivocally that he was aware of these cases when they appeared in the literature, even before the warnings were added to the label for Remicade®, and that as soon as he learned of these cases, he made it his practice to warn all of his patients for whom he recommended TNF blockers in combination with mercaptopurine, including Mr. Wendell, of this possible risk. Dr. Rich testified that he continued to prescribe these medications to his patients, including Mr. Wendell, after he became aware of the precise alleged risk associated with these therapies.

Dr. Rich's testimony irrefutably establishes that the warning Plaintiffs argue was required would not have changed his decision to prescribe mercaptopurine to Mr. Wendell. For these reasons, Plaintiffs cannot establish the element of causation required to make out both their strict liability and negligence claims against GSK. Accordingly, GSK's motion for summary judgment should be granted.

II. STATEMENT OF FACTS

A. Decedent's Medical History

Decedent Maxx Wendell was referred to Dr. Edward J. Rich, a pediatric gastroenterologist, in 1998 at age twelve. Declaration of William A. Hanssen ("Hanssen Decl.") ¶2, Ex. A (Transcript of Deposition of Dr. Edward J. Rich ("Rich Dep.") 38:6-18, 49:25-50:13). Dr. Rich diagnosed Mr. Wendell with ulcerative colitis ("UC"), a type of inflammatory bowel disease ("IBD"). *Id.* at 59:19-23, 69:4-70:1. Dr. Rich prescribed Prednisone (a steroid) and Asacol (an anti-inflammatory) to treat Mr. Wendell's IBD. *Id.* at 71:3-72;23, 75:2-12, 82:3-8. These medications did not adequately control Mr. Wendell's IBD so Dr. Rich added Purinethol® to the regimen in July 1999 *Id.* at 78:16-82:2, 83:11-20, 85:1-86:22, 105:6-15. Dr. Rich wanted to discontinue Prednisone because of his concern about the side effects of continued long-term use of Prednisone, including osteoporosis and diabetes. *Id.* at 82:9-83:10, 86:13-87:10.

In May 2002, Dr. Rich began to discuss adding Remicade®, a tumor necrosis factor blocker ("TNF blocker") to Mr. Wendell's drug regimen. *Id.* at 117:4-118:1, 122:10-123:10. He began to prescribe Remicade® in July 2002 and it very effectively controlled Mr. Wendell's IBD symptoms. *Id.* at 147:24-148:16, 151:14-152:8, 153:22-154:16. Dr. Rich continued quarterly infusions in combination with mercaptopurine until March 2006. *Id.* at147:24-148:16, 177:12-24. In November 2005, Dr. Rich began discussing with Mr. Wendell and his mother the possibility of discontinuing TNF blockers completely or switching to Humira®, a newer TNF blocker that is self administered via subcutaneous injection. *Id.* at 170:24-173:5. Since Mr. Wendell's IBD symptoms were well-controlled, Dr. Rich discontinued Remicade® in March 2006. *Id.* at 198:1-199:7.

After Mr. Wendell's IBD flared in November 2006, Dr. Rich prescribed Humira® injections in addition to mercaptopurine. *Id.* at 200:2-19, 216:25-217:10. Mr. Wendell was diagnosed with HSTCL in July 2007. (FAC ¶58)

B. Dr. Rich's Knowledge About Mercaptopurine

Dr. Rich learned about the off label use of mercaptopurine to treat IBD during his fellowship training at the University of California, San Francisco *Id.* at 84:1-15, 37:9-38:2. When Dr. Rich decided to prescribe mercaptopurine to Mr. Wendell in 1999, he did so based on information he obtained during his fellowship training, reviewing medical literature, consulting with other professionals in his field and attending medical conferences. *Id.* at 274:10-275:1. He does not know if he ever read the label for mercaptopurine, but he cannot remember doing so and has no recollection of its content or relying upon it. *Id.* at 281:11-284:4, 285:18-21. He did not know what the FDA approved indication is for mercaptopurine. *Id.* at 83:21-25. It is not his regular practice to look at drug labeling and he receives information on medications "from many places, articles, literature, meetings, professionals in the field." *Id.* at 192:2-10. He has never discussed mercaptopurine with any pharmaceutical sales representative. *Id.* at 20:5-8.

Well before Dr. Rich prescribed mercaptopurine to Mr. Wendell he was aware of a medical article that reported a case of lymphoma (not HSTCL) in a patient using mercaptopurine. *Id.* at 89:12-90:17. Dr. Rich knew the risk was a possibility and advised his patients to whom he prescribed mercaptopurine, including Mr. Wendell and his family, that "there is a small, but non-zero increased risk of infections and malignancies, and I may or might not have said 'including lymphoma' when I discussed 6-MP (mercaptopurine)." *Id.* at 88:10-89:11.

C. Reports Are Made Public of Hepatosplenic T-cell Lymphoma in Patients Taking Remicade® in Combination With Mercaptopurine

In May 2006, the FDA approved Remicade® for an additional indication — the treatment of active pediatric Crohn's disease. FAC at ¶39. In addition to the changes to the Remicade® label related to the new indication, the FDA required the inclusion of a black box warning to report six post-marketing cases of HSTCL in pediatric patients or young adults taking Remicade® in conjunction with either

mercaptopurine or azathioprine (another immunosuppressant). *Id.* at ¶40. The manufacturer of Remicade® sent out a Dear Health Care Practitioner letter shortly after it received FDA approval of the language, including the additional warning information based on the six post-marketing cases of HSTCL. Hanssen Decl. ¶2, Ex. A (Rich Dep. 200:1-202:22).

D. Dr. Rich Becomes Aware of The Reported Risks of TNF Inhibitors Taken Alone or in Combination With Mercaptopurine and Continues to Prescribe These Medications for Mr. Wendell Despite Those Risks

Dr. Rich testified that TNF inhibitors were an important part of his treatment of patients with inflammatory bowel disease. *Id.* at 250:17-252:7. He stayed abreast of changing information about the risks reported with these drugs (1) by attending conferences and regional meetings of gastroenterologists, (2) through discussions with pediatric and adult gastroenterologist colleagues, and (3) by reading case reports, reports of clinical studies of these medications, and articles published in the field. *Id.* at 250:17-252:7, 191:24-192:10, 193:23-194:18, 124:24-126:3, 132:25-133:25. He would have received the May 2006 Dear Health Care Practitioner letter *Id.* at 199:20-202:22, but through his monitoring of the literature in the field he was already aware of the post-marketing cases of HSTCL before he received the letter and before the black box warning regarding HSTCL was added to Remicade®. *Id.* at 214:23-215:22, 200:20-202:22, 203:18-207:5.

As soon as he became aware of these reports, Dr. Rich began warning all of his patients taking TNF inhibitors, including Mr. Wendell, of the specific risk of HSTCL. *Id.* at 209:6-210:4, 214:23-215:22; 241:4-21. He became aware of the risk of HSTCL associated with these medications from medical literature in 2005 and "would have discussed this risk before the black box warnings." *Id.* at 209:6-210:12, 204:16-205:23, 214:23-215:22; 241:4-21. He "would have and did discuss this risk with the Wendell family and all of his patients on these medications." *Id.* at

209:6-210:12. He continued to prescribe Mr. Wendell Remicade® in combination with mercaptopurine in 2006 after he became aware of the reports relating to HSTCL. *Id.* at 214:23-215:22. He believed that the association between HSTCL and therapy with Remicade® in combination with immunosuppressants such as mercaptopurine applied to the entire class of TNF inhibitors, including Humira. *Id.* at 137:21-138:5, 264:21-265:19. After discussing with Mr. Wendell "the specific increased risk of hepatosplenic T-cell lymphoma" (*Id.* at 265:4-19, 241:4-21), Dr. Rich reinitiated anti-TNF therapy after Mr. Wendell experienced an IBD flare in November 2006, prescribing Humira in combination with mercaptopurine. *Id.* at 227:10-228:12.

III. ARGUMENT

A. Summary Judgment Standard

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Fed. R. Civ. P.* 56(c)(2). "[T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is 'entitled to a judgment as a matter of law' because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex v. Catrett* (1986) 477 U.S. 317, 323-324, 106 S. Ct. 2548, 91 L. Ed. 2d 265. *See* also *Union Bank v. Superior Court*, (1995) 31 Cal. App. 4th 573, 37 Cal. Rptr. 2d 653.

The moving party can meet its burden of proof on summary judgment by pointing out the absence of evidence from the non-moving party. *Celotex, supra,* 477 U.S. 317, 322-323, 327. Once such affirmative evidence is presented, the burden then shifts to plaintiff to demonstrate a triable issue of fact. *Anderson v. Liberty Lobby, Inc.* (1986) 477 U.S. 242, 250. As set forth above, the undisputed facts show that there is no evidence that Dr. Rich would have altered his decision to prescribe (mercaptopurine) Purinethol® if the drug's package insert had included a warning of the risk of hepatosplenic T-cell lymphoma. Each of Plaintiffs' claims for relief against GSK based on a theory of failure to warn must therefore fail as a matter of law, entitling GSK to summary judgment.

B. Plaintiffs Have Not Established that a Failure to Warn by GSK Caused Decedent's Alleged Injuries

It is well-settled in California that a manufacturer of prescription drugs owes to the medical profession the duty of providing adequate warnings if it knows, or has reason to know, of any dangerous side effects of its drugs. *Carlin v. Superior Court of Sutter County* (1996) 13 Cal. 4th 1104, 1112-1113, 56 Cal. Rptr. 2d 162. California follows the learned intermediary doctrine, which states that in the case of prescription drugs, the duty to warn "runs to the physician, not to the patient." (Citations omitted). *Id.* at 1116. A manufacturer therefore discharges its duty to warn if it provides adequate warnings to the physician about any known or reasonably knowable dangerous side effects, regardless of whether the warning reaches the patient. *Motus v. Pfizer* (2001) 196 F.Supp.2d 984, 990-991. A plaintiff asserting causes of action based on a failure to warn must prove not only that no warning was provided or the warning was inadequate, but also that the inadequacy or absence of the warning caused the plaintiff's injury. (Citations omitted.) *Id.* at 991.

The Ninth Circuit has held that under California law a product defect claim based on insufficient warnings cannot survive summary judgment if stronger

warnings would not have altered the conduct of the prescribing physician." *Motus v. Pfizer, Inc.*, 358 F.3d 659, 661 (9th Cir. 2004) (affirming grant of summary judgment for defendant on basis that manufacturer's alleged failure to provide adequate warnings did not cause patient's suicide); *see also Ramirez v. Plough, Inc.*, (1993) 6 Cal. 4th 539, 556 (holding, under similar circumstances, that "there is no conceivable causal connection between the representations or omissions that accompanied the product and plaintiff's injury"). Moreover, a plaintiff cannot prove that an allegedly inadequate warning was the proximate cause of his or her injury where the treating physician knew of the risk at issue as "no one needs notice of that which he already knows." *See, e.g., Plummer v. Lederle Laboratories, Div. of American Cyanamid Co.*, 819 F.2d 349, 359 (2d Cir. 1987) (relied on by the Ninth Circuit in *Motus v. Pfizer Inc.* 358 F.3d 659 (Roerig Div.) (9th Cir. 2004)) (citation omitted).

1. Plaintiffs Cannot Prove That Purinethol® Was The Proximate Cause of Their Alleged Injuries.

Dr. Rich prescribed mercaptopurine to Mr. Wendell after knowing of the precise alleged risk Plaintiffs argue GSK should have warned about. Therefore, Plaintiffs cannot meet their burden of showing that GSK's alleged failure to warn was the legal cause of Mr. Wendell's injury. In *Motus*, the district court granted summary judgment for Pfizer, holding that the plaintiff had failed to create a genuine issue as to whether Pfizer's alleged failure to adequately warn of the risk of suicide associated with Zoloft caused her injuries because the prescribing physician testified that he did not rely on any statements or written materials from Pfizer in making his decision to prescribe Zoloft. *Id.* at 996, 999. The Ninth Circuit affirmed, finding that in light of this testimony, stronger warnings would not have altered the physician's conduct. *Motus*, 358 F.3d at 661 (finding "the adequacy of Pfizer's warnings. . .irrelevant to the disposition of this case.").

In evaluating the causation requirement in *Motus*, the Ninth Circuit relied on a Second Circuit case, *Plummer*. *Motus*, 358 F.3d at 661. In *Plummer*, the treating physician testified that he knew of the risk of contact polio plaintiff argued defendant should have warned about, but prescribed defendant's vaccine without warning the patient's mother of that risk. 819 F.2d at 358-59. The court held that on these facts, judgment notwithstanding the verdict should have been entered for the defendant because "a reasonable jury could not have found proximate cause." *Id.; see also Plenger v. Alza Corp.*, (1992) 11 Cal. App. 4th 349, 362 ("We are aware of no authority which requires a manufacturer to warn of a risk which is readily known and apparent to the. . .physician."); *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) ("If the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of warning is not a producing cause of injury."); *Dunn v. Lederly Labs.*, 328 N.W.2d 576, 582 (Mich. Ct. App. 1982) (affirming jury verdict for defendant where doctor testified he was aware of the risk plaintiffs argued defendant should have warned of).

Here, as in *Motus* and *Plummer*, Plaintiffs cannot establish that a stronger warning would have altered the conduct of the prescribing physician and therefore cannot meet their burden of proving causation. Plaintiffs allege that GSK should have known that its drug ". . .used either singly or in combination with TNF-blocking drugs like Remicade® and/or Humira®, posed a risk of hepatosplenic T-cell lymphoma but negligently failed to discover this risk and/or failed to provide a timely or adequate warning about such risk." FAC ¶93. But Dr. Rich's testimony firmly establishes that he was apprised of the potential risks of mercaptopurine from his own efforts. *See supra* Sections II.B., D. In short, even if the warning Plaintiffs argue was required had been provided, it would have had no impact on Dr. Rich's decision to prescribe mercaptopurine to Mr. Wendell.

Dr. Rich testified that he learned of the cases of HSTCL reported in patients taking Remicade® in combination with mercaptopurine in 2005 when they were reported in the literature. Hanssen Decl. ¶2, Ex. A (Rich Dep. 214:23-215:22). As soon as he became aware of these reports, he began warning all of his patients taking TNF inhibitors in combination with mercaptopurine including Mr. Wendell, of the specific potential risk of HSTCL. *Id.* at 214:23-215:22, 214:4-21. He continued prescribing Remicade® in combination with mercaptopurine for Mr. Wendell in 2006 even after he learned of these reports. *Id.* at 214:23-215:22. In early 2006, he discontinued Mr. Wendell's use of Remicade®, but reinitiated anti-TNF therapy with Humira in November 2006 when Mr. Wendell again experienced an IBD flare. *Id.* at 215:15-22, 216:10-217:10. Dr. Rich testified that he believed that the reported risk for HSTCL applied to all TNF inhibitors, including Humira (*Id.* at 264:21-265:19) and that he discussed with Mr. Wendell "the specific increased risk of hepatosplenic T-cell lymphoma" before prescribing Humira. *Id.* at 265:4-19. Dr. Rich prescribed Humira in combination with mercaptopurine with knowledge of these alleged risks. *Id.* at 227:10-228:12.

Dr. Rich's testimony incontrovertibly establishes that a stronger warning about HSTCL would not have changed his decision to prescribe mercaptopurine in combination with TNF blockers to Mr. Wendell. Because "stronger warnings would not have altered the conduct of the prescribing physician[,]" Plaintiffs' "product defect claims based on insufficient warnings cannot survive summary judgment." 358 F.3d at 661; *see also Ferguson v. Proctor & Gamble Pharms., Inc.*, 353 F.Supp. 2d 674, 679 (E.D. La. 2004) (granting summary judgment based on the prescribing physician's representation that he would have prescribed the drug knowing of the risk of developing the condition of which plaintiff suffered). Further, as in *Plummer*, "no harm could have been caused by failure to warn of a risk already known." *Plummer*, 819 F.2d at 359 (citing *Rosburg v. Minn. Mining & Mfg. Co.*, (1986) 181 Cal. App. 3d 726, 730; *see also In re Zyprexa Prods. Liab. Litig.*,

Nos. 04-MD-1596, 06-CV-2782, 2009 WL 1852001, at *14-15 (E.D.N.Y. Jun. 22, 2009) (applying California law and concluding that a different warning would not have "caused any different medical decisions" where the record showed that the doctors "were aware of Zyprexa's risks related to [plaintiff's injuries]"); *Huntman v. Danek Med., Inc.*, No. 97-2155, 1998 WL 663362, at *5 (S.D. Cal. July 24, 1998) (holding, in the medical device context, that "the adequacy of the warnings is immaterial where the doctor knows of the specific risks," citing *Rosburg*, 181 Cal. App. 3d at 735).

Plaintiffs' claims against GSK for negligence and strict liability should be dismissed.

2. GSK's Warnings Are Irrelevant to The Disposition of This Case Because Dr. Rich Does Not Recall Reading the Warnings and Did Not Rely Upon Them in Deciding to Prescribe Mercaptopurine.

A product defect claim based on insufficient warning cannot survive summary judgment if there is no evidence that a stronger warning would have altered the conduct of the prescribing physician. *Motus v. Pfizer* (2004) 358 F.3d 659, 661. And when a doctor testifies that he did not read or rely upon the warning label, the adequacy of the label is irrelevant to the disposition of the case. In *Motus,* the prescribing physician testified that he did not read the warning label that accompanied the drug at issue or rely on information provided by the manufacturer's sales representatives before prescribing the drug to the decedent. As such, the court concluded, the adequacy of the drug company's warnings was irrelevant to the disposition of the case. *Id.*

Here, as in *Motus,* Dr. Rich testified that he does not recall reading or relying upon the Purinethol®/mercaptopurine warning label in deciding to prescribe it to Mr. Wendell. Hanssen Decl. ¶2, Ex. A Dep. of Dr. Rich at 281:11-284:4; 285:18-21. Dr. Rich testified that his sources of information about mercaptopurine at the time he first prescribed it to Mr. Wendell were training during his fellowship

at the University of California San Francisco; reviewing the medical literature; conferring with other physicians; and attending medical conferences. *Id.* at 274:10-275:1. He cannot recall reading the mercaptopurine label and has no recollection of its content. *Id.* at 281:11-284:4; 285:18-21. Moreover, it is not his regular practice to look at drug labeling because he receives information on medications "from many places, articles, literature, meetings, professionals in the field, *et cetera*." *Id.* at 192:2-10. He has never discussed mercaptopurine with any pharmaceutical sales representative. *Id.* at 20:5-8.

In short, there is no evidence that Dr. Rich read or relied upon GSK's published warning label about mercaptopurine/Purinethol® or relied upon any information from GSK sales representatives before prescribing it to Mr. Wendell. As in *Motus*, these facts preclude Plaintiffs from establishing a sufficient causal link between their injury and GSK's conduct. *Id.* at 660. Accordingly, the adequacy of GSK's warning is irrelevant to the disposition of this action and GSK is entitled to summary judgment.

IV. CONCLUSION

Based on the foregoing, GSK respectfully requests that the Court enter summary judgment in its favor and dismiss Plaintiffs' Fourth Amended Complaint as to GSK in its entirety, with prejudice.

DATED: July 7, 2011

DRINKER BIDDLE & REATH LLP

By: _____

William A. Hanssen
Suzanne V. Stouder
Attorneys for Defendant
GLAXOSMITHKLINE LLC,
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